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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,772

02/22/2002

Janet K. Yamamoto

UF-267XC1

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01/23/2008

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EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/080,772

Applicant(s)

YAMAMOTO ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 36-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 10/080,772
Applicants: Yamamoto, J. K., et al.

Docket No.: UF-267XC1
Filing Date: 02/22/2002

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 22 December, 2006. Claims 1-28 and 36-46 are pending in the instant application. Applicants' election of Group I (claims 1-14) without traverse is acknowledged. Claims 15-28 and 36-46 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.98

The information disclosure statement filed 19 March, 2004, has been placed in the application file and the information referred to therein has been considered. Applicants are reminded that the listing of references in the specification is not a proper information disclosure statement (see pp. 33-38). 37 C.F.R. § 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and M.P.E.P. § 609.04(a), subsection I. states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims are directed toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. The reference to an "immune response" is vague and indefinite. First, the nature of the immune response (i.e., protective, therapeutic, humoral, cell-mediated, complement, etc.) desired is not readily manifest. Second, FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera et al., 2000). Thus, it is not readily manifest what purpose the immune response serves. Finally, the claims are also incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The claims fail to recite any positive methods steps following the administration step that result in the confirmation of the desired immune response. For instance, if the claims were directed toward a method of inducing cross-neutralizing antibodies between FIV and HIV-1, the methods would generally comprising an administration

step and minimally, a detection step to identify if said antibodies were present in the host. Appropriate correction and clarification are required.

35 U.S.C. § 101

The following is a quotation of 35 U.S.C. § 101 which reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific, substantial, and/or credible utility, or a well-established utility. The claims are drawn toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera et al., 2000). Butera and colleagues (2000) examined a cohort of veterinarians for exposure to both FIV and FeLV and concluded that "The absence of identifiable feline retroviral zoonosis among this highly exposed cohort strongly supports the view that these feline viruses pose little threat to individual humans or to public health" (see left column, p. 1478). Poeschla and Looney (1998) reviewed the prior art and noted that "Neither human seroconversion nor any other detectable evidence of human infection or disease occurs, despite frequent exposure of humans to FIV by biting, the

principal route of natural feline transmission" (see bridging paragraph, p. 6858). The term "infection" references the characteristic of a disease-causing agent that is capable of entering, multiplying, surviving, and causing disease in the host.¹ The purpose of inducing an immune response appears to be for the purpose of preventing and/or treating infection (see specification, p. 10). No other uses are disclosed in the specification. However, since FIV does not establish a productive infection in non-feline hosts and said hosts are clearly not susceptible to infection by FIV, it is not readily manifest what purpose the induction of an immune response in this setting serves. Accordingly, the claimed invention lacks both a specific and substantial utility.

Claims 1-14 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

¹ Stedman's Online Medical Dictionary, 2008, Lippincott Williams & Wilkins; Merriam-Webster Online Dictionary, 2005, Merriam-Webster, Incorporated.

Enablement

Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed *supra*, the claims are drawn toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. The purpose of inducing an immune response appears to be for the purpose of preventing and/or treating infection (see specification, p. 10). No other uses are disclosed in the specification.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide sufficient guidance demonstrating that humans, and other non-felines, are productively infected by FIV. The term "infection" references the characteristic of a disease-causing agent that is capable of entering, multiplying, surviving, and causing disease in the host.² FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera et al., 2000). Butera and colleagues (2000) examined a cohort of veterinarians for exposure to both FIV and FeLV and concluded that "The absence of identifiable feline retroviral zoonosis among this highly exposed cohort strongly supports the view that these feline viruses pose little threat to individual humans or to public health" (see left column, p. 1478). Poeschla and Looney (1998) reviewed the prior art and noted that "Neither human seroconversion nor any other detectable evidence of human infection or disease occurs, despite frequent exposure of humans to FIV by biting, the principal route of natural feline transmission" (see bridging paragraph, p. 6858). Thus, the induction of an immune response for therapeutic or prophylactic purposes seems unlikely.

2) The disclosure fails to provide sufficient guidance or direction pertaining to the nature of the desired immune response. As note *supra* in item (1), FIV does not establish a productive infection in human or non-feline hosts. Thus, it is not readily manifest what type of immune response the induction of an FIV immunogen will produce (i.e., humoral, cell-mediated,

² Stedman's Online Medical Dictionary, 2008, Lippincott Williams & Wilkins; Merriam-Webster Online Dictionary, 2005, Merriam-Webster, Incorporated.

neutralizing antibody, cytotoxic T-lymphocyte (CTLJ), complement, etc.).

3) The disclosure fails to provide any working embodiments. It was reported in the disclosure that two human subjects generated antibodies specific for FIV suggesting previous exposure to FIV. However, the specification clearly states that "Both of the human subjects infected with FIV identified thus far are currently clinically and immunologically asymptomatic" (see specification, p. 8). Thus, the data provided in the specification clearly demonstrates that FIV does not establish a productive infection in human hosts. This may be due, inter alia, to the inability of human cells to support FIV replication, the absence of suitable receptors and coreceptors on the cell surface of human cells, or the generation of a robust immune response that clears the virus before it can establish a productive infection. In any event, the disclosure fails to provide any working embodiments wherein an FIV immunogen was administered to induce a protective or therapeutic immune response against FIV.

4) The prior art demonstrates that FIV does not productively infect humans or non-felines (see item (1) *supra*). Thus, it is not readily manifest what type of immune response should be generated by the claimed invention.

Accordingly, when all the aforementioned items are considered *in toto*, it would clearly require undue experimentation to practice the claimed invention.

Correspondence

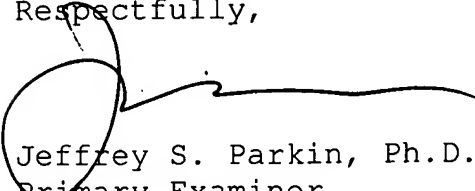
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the

examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

20 August, 2007